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09/784,949	02/15/2001	Arthur Campbell	PD-0387	4193

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EXAMINER

LAM, ANN Y

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 07/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/784,949

Applicant(s)

CAMPBELL ET AL.

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The limitation regarding the selection of one of the menu items to cause the drive mechanism to reverse direction, as recited in claim 12, is not found by Examiner in the written description in the specification.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1, 3-8 and 15-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Peterson et al., 5,935,099. Peterson et al. discloses a drive mechanism (140) that forces the fluid out of a reservoir; an input device, see column 25, lines 47-48; a processor (182); a display that receives information from the processor and visually displays one or more screens containing the information, see column 25, line 51; wherein at least one of the one or more screens includes a menu with at least two menu items, see column 25, line 56-57, and wherein the input device is used to select one menu item from amongst the at least two menu items, see column 25, lines 47-48.

As to claims 3, 18, 39 and 40, the system includes a means to store a maximum bolus that is programmable using the input device, wherein the maximum bolus limits the maximum units of fluid that can be delivered in a single bolus, see column 13, line 39. As to claims 39 and 40, the bolus is considered to be an express bolus or an easy bolus.

As to claims 4 and 17, the system includes a means to store a maximum basal rate as claimed, see column 8, line 46.

As to claim 5, the system includes a means to store one or more basal profiles as claimed, see column 8, line 46.

As to claim 6, the system includes one or more alarm types as claimed, see column 35, line 64.

As to claims 7 and 20, the system includes a means (182) to store an insulin type.

As to claims 8 and 21, the system includes a means (182) to store a reservoir type as claimed.

As to claims 15 and 41 the screen is considered to be a status screen, see column 25, lines 47-67.

As to claims 16 and 19, the one or more screens is considered to include one or more set or select screens, see column 25, lines 47-67.

As to claim 22, the one or more select screens is considered to include a screen to select a language.

As to claim 23, a housing as claimed is disclosed at (106).

As to claim 24, an infusion set and tubing as claimed is disclosed at (110).

As to claims 25 and 26, a manual prime or a fixed prime may be used to fill the tubing with fluid from the reservoir, see column 25, lines 60-62, and column 43, lines 51-60, and column 44, lines 29-38.

As to claim 27, the information is considered to be shown on the display screen to guide an individual through the steps to prime the infusion system, see column 25, lines 59-60.

As to claim 28, one of the at least two menu items is highlight when the menu is displayed, see column 25, lines 54-58.

As to claim 29, the one of at least two menu items that is highlighted when the menu is displayed is considered dependent on a function that the infusion system is performing when the menu is displayed, see column 25, lines 54-58.

As to claim 30, the system further includes a communication device, see column 25, lines 14-18.

As to claim 31, selection of at least one of the at least two menu items causes the display to show a screen that allows an individual to signify the identity of a device, which thereby configures the infusion system to accept communication from the device, see column 25, lines 14-17.

As to claim 32, the input device includes a keypad, see column 25, lines 47-48.

As to claim 33, when the infusion system is suspended from delivering fluid, fluid delivery is resumable with two or less keystrokes independent of the screen being displayed, see column 25, lines 62-63.

As to claim 34, the ENTER/CLEAR key in column 25, line 53 is equivalent to an ACT key as claimed.

As to claims 35, 36 and 43, the ENTER/CLEAR key in column 25, line 53 is equivalent to an Esc key as claimed, since the system is capable of performing the claimed function.

As to claims 37 and 38 a single keystroke is used to exit a Blank Screen and display at least one other screen, such as a Main Menu screen, see column 25, lines 51-52.

As to claim 42, the method steps are disclosed in column 25, lines 47-67.

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As to claim 44, the screen is considered to select a therapy.

As to claim 45, the input device is considered to include soft keys.

As to claim 46, the screen is considered to be a confirmation screen.

3. Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by DeLaHuerga, 6,408,330. DeLaHuerga discloses a drive mechanism, see column 17, line 51, an input device, a processor (194), a screen (523) with a menu, see column 29, lines 62-64, as claimed, wherein the processor runs energy management software that changes the display to a Blank Screen after a Time-Out delay has expired, see column 25, lines 22-34.

4. Claims 1, 7, 9, 10 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Coutre et al., 5,153,827. Coutre et al. discloses a drive mechanism, an input device, a processor, a screen and menu, as claimed.

As to claims 7 and 20, the system includes a means to store an insulin type, see column 15, line 42.

As to claims 9, 10 the system includes a means to reset control parameters to factor default values or values set by a health care professional, see column 5, lines 60-67.

5. Claims 1 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Say et al., 6,175,752. Say et al. discloses a drive mechanism (260), an input device

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(162), a processor, a screen and menu, see column 53, lines 226-27, as claimed. As to claim 11, the system includes an alarm wherein the alarm intensity changes with time, see column 46, lines 9-23.

6. Claims 1 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Lundquist et al., 5,011,468. Lundquist et al. discloses a drive mechanism, an input device (171), a processor, a screen and menu, see column 9, lines 37-46, as claimed. As to claim 12, at least one of the menu items is considered to cause the drive mechanism to reverse direction, see column 10, lines 41-47.

7. Claims 1 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Benkowski et al., 6,183,412. Benkowski et al. discloses a drive mechanism (12), a processor (80), an input device, a screen and menu, see column 12, lines 38-4, as claimed. As to claim 13, selection of at least one of the at least two menu items causes the infusion system to begin a selftest, see column 5, lines 51-52.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.



8. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al., 5,935,099, in view of Havel, 5,003,298.

Peterson et al. discloses the invention substantially as claimed, see above. However, Peterson et al. does not disclose a numeric value displayed on the screen wherein a number to the right of a decimal point is formatted differently than a number to the left of the decimal point.

Havel discloses a display wherein the digits that precede the decimal point are illuminated in a first color, and digits that follow the decimal point are in a second color, to more effectively emphasize the position of the decimal point, see column 1, lines 47-52, and column 3, lines 51-58. The number to the right of the decimal point is considered to be formatted differently than a number to the left of the decimal point. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the format for the digits to the right and left of a decimal point as taught by Havel in order to emphasize the position of the decimal point for easier reading.

### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on T-F 8-6:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (703)308-3552. The fax phone numbers

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for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

A.L.   
June 28, 2002

  
ANH TUAN T. NGUYEN  
PRIMARY EXAMINER

6/29/02